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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,906	04/02/2001	Micheal L. Gruenberg	24731-500G	9764

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MORRISON & FOERSTER LLP  
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SAN DIEGO, CA 92130-2332

EXAMINER
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SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 10/03/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/824,906

Applicant(s)

GRUENBERG, MICHEAL L.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-101 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-101 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other:

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1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims 1-70 drawn to a method of growing cells, classified in class 435, subclass 2.
  - II. Claims 71,72,77,100,101 drawn to a cell composition, classified in class 435, subclass 325.
  - III. Claims 73,74,76 are drawn to a method of treating infectious disease, classified in Class 424, subclass 93.1.
  - IV. Claims 73-75,79-91,97-99 are drawn to a method of treating autoimmune disease, classified in Class 424, subclass 93.71.
  - V. Claims 78,92-96 are drawn to a method of treating transplant rejection, classified in Class 424, subclass 93.7.
2. The inventions are distinct, each from the other because of the following reasons.
3. Inventions I,III-V are different methods. These inventions require different ingredients and process steps to achieve different goals. Invention I is a method of growing cells whilst inventions III-V are methods of treating diseases. Regarding the methods of Inventions III-V, said inventions use cells derived from different pathologic conditions wherein the cells are structurally and functionally unique (eg. cells that recognize alloantigens, versus cells that recognize pathogens, versus cells that recognize autoimmune antigens, etc). The cells of inventions III-V are given to different types of patients that are suffering from the particular types of disease recited in the claims. Therefore they are novel and unobvious in view of each other and are patentably distinct.
4. Inventions II and III-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cells could be used as an immunogen to produce antibodies which bind cell surface markers found on said cells.

5. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the claimed cells could be made by growing cells and later isolating the Th2 cells (eg. in the absence of a step wherein cells are treated in vitro to differentiate into Th2 cells).

6. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-V is not required for any other group from Groups I-V and Groups I-V have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. The following species elections are required (as they pertain to the invention elected above).

9. This application contains claims directed to the following patentably distinct species of the claimed invention.

1) The method of growing cells that uses IL-4 or IL-12 or gamma interferon or a particular combination of said agents.

The aforementioned cytokines are chemically and structurally distinct.

2) The method of growing cells that uses one of the antibody combinations recited in claim 8.

The aforementioned antibodies are chemically and structurally distinct.

3) The method or composition wherein the cells are CD8 or CD4 positive.

The aforementioned cells are chemically and structurally distinct.

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4)The method wherein the autoimmune disease is one of the diseases recited in claim 75.

The diseases have differing art recognized mechanisms and pathologies.

5) The method wherein the infectious disease is one of the diseases recited in claim 76. The diseases are caused by different infectious agents.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).


Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

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RONALD B. SCHWADRON  
PRIMARY EXAMINER  
GROUP 1800 1644

Ron Schwadron, Ph.D.

Primary Examiner

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